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09/784,980	02/16/2001	Anthony John Bell	5641C1-07-LAV	5253

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EXAMINER

CHAWLA, JYOTI

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

09/784,980

Applicant(s)

BELL ET AL.

Examiner

Jyoti Chawla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 46-55 is/are pending in the application.
- 4a) Of the above claim(s) 10-27 and 46-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 28-36 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 03, 2006 has been entered. Claims 37-45 have been cancelled and claim 55 has been added. Claims 1-36 and 46-54 are pending in the application. Claims 10-27 and 46-54 were withdrawn from further consideration as being directed to a non-elected invention. Claims 1-9, 28-36 and 55 are examined in the present office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 28 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

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had possession of the claimed invention. The term “a chemically induced unpleasant mouthfeel” was not described in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 28 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “a chemically induced unpleasant mouthfeel” in Claims 1, 28 and 55 is a relative term which renders the claims indefinite. The term “a chemically induced unpleasant mouthfeel” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term “unpleasant mouthfeel” is indefinite as a food or flavor that might have unpleasant mouthfeel for some, would be desirable for others.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(A) Claims 1, 2, 4-9, 28, 29, 31-36 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsuragi et al. (EP 0732064 A1) in view of the combination of Sharma et al (US 4797288) and Oravainen (WO9107100).

Katsuragi et al., hereinafter Katsuragi, teaches a bitterness relieving agent for food, medicine, cosmetic uses. Katsuragi teaches adding at least one botanical, such as Ginkgo biloba to lozenges, or hard-boiled candies, troches etc., and providing a bitterness-relieving agent to suppress the unpleasant mouthfeel associated with a botanical (Page 4, lines 9-10, 26-37 and 57), as recited in claims 1,2,28,29 and 55.

Katsuragi teaches that the bitterness-relieving agent comprises an ester of a glyceride (mono/di-glyceride and triglycerides, i.e., fats and oils) with a carboxylic acid ( e.g., citric acid is a polycarboxylic acid) or salt thereof. Katsuragi teaches that the preferred fatty acids (either saturated or unsaturated) range from 8-22 carbon atoms, including lauric acid, stearic acid, oleic acid, linoleic acid and linolenic acid (Page 3, lines 3-20). Katsuragi further teaches that bitterness relieving agent can be dissolved in edible oils (hydrogenated, transesterified or regular), such as palm kernel oil, milk fat and cottonseed oil to name a few, before being added to food (Page 3, line 58 to Page 4, line7) as recited by the applicant 1,4,5, 28,31, 32, 55. Thus Katsuragi teaches a fat soluble bitterness relieving composition using esterified fatty acids with glycerol, and polycarboxylic acid (e.g., citric acid).

Sharma et al, hereinafter Sharma, teaches a novel drug delivery system that masks the unpleasant taste of the pharmaceutical drugs, while protecting the drugs from damaging

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effects of moisture, temperature and pH. The taste masking composition includes 61-95% hydrophobic edible material, mainly fatty acids and waxes (lipids) such as hydrogenated oils of palm, palm kernel, cottonseed etc., and mixtures thereof (Column 3, line 64-column 5, line 41). Sharma further teaches that the amount of drug or salt of a drug in relation to the weight of the coating matrix is 1-75% (Column 5, lines 24-28), thus making the ratio of taste modifier fat and wax composition 61:1 or 1: 0.017 to about 1:1 as recited by the applicant in claims 1,8, 9, 35,36. Since Sharma teaches addition of hydrogenated fats and waxes (fats) in the amount of 61-95% in the coating matrix to reduce the bitterness, therefore it would be obvious to one of ordinary skill in the art that Sharma teaches of a bitterness relieving compound that consists essentially of fats as recited by the applicant in claims 1 and 28 as well as in claim 55.

Oravainen et al., hereinafter Oravainen, teaches addition of oil to hard candy to prevent sticking during formation of the candy and make the product more opaque. In one example, Oravainen et al. teach adding 1% oil (Abstract, Page 7, lines 15-25, Example 3) as recited by the applicant in claims 1, 6, 7, 28, 33, 34 and 55.

Hard candy with fat has been known in the art (Oravainen). Candies with botanicals with unpleasant mouthfeel (Ginkgo-biloba) have been known (Katsuragi). The esterified fatty acids as fats or milk fats or oils have been known additives to the art of candy making (Werther's original candy by Stork). Similarly polycarboxylic acids like citric acid have been utilized in the confectionery art as humectants, acidifiers and sometimes as

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antioxidants. Bitterness relieving compounds containing fats or fat based compounds in varying proportions have also been known in the confectionery as well as in pharmaceutical industry (Katsuragi and Sharma). It has also been known that the bitterness relieving agent taught by Katsuragi is soluble in fats, such as, cottonseed oil, palm kernel oil, butter etc. Therefore, it would have been obvious to one of ordinary skill in the art to modify composition taught by Katsuragi and dissolve the ester in fat as taught by Sharma and Katsuragi before adding to hard candy, in order to ensure that the unpleasant mouthfeel of the botanical was reduced or suppressed. One would have been further motivated to dissolve the bitterness relieving composition of Katsuragi in saturated fats or oils, to make a candy that moulds to various shapes without sticking either to the mold or to consumer's hands.

Regarding the amount of bitterness relieving agent as recited in claims 1,6,7,28,33,34 and 55, or ester, Katsuragi teaches that 0.01-10% of the compound is effective to suppress the unpleasant mouthfeel of the botanical (Page 4, line 42-45), by dissolving the ester in the oil, the resulting oil becomes effective to suppress the unpleasant mouthfeel. Katsuragi does not explicitly teach the quantity of oil that is effective to suppress the unpleasant mouthfeel as recited in claims 1,6-9,28,33-36 (See Abstract, Page 3, lines 9-13, Page 3, line 58 to Page 4, line 5, Page 4, lines 25-47, Examples 3 and 4, Claims). However, to select any particular level of the effective oil, such that the level is 0.5-5%, 0.5-3.5%, or 0.75 to 3.0% in the hard candy as recited in claims 1, 6, 7, 28, 33, 34 and 55 would have been obvious depending on

- (1) the bitterness of the botanical included,
- (2) the amount of botanical included,
- (3) the particular amount of ester required to suppress the unpleasant mouth feel of the botanical, and
- (4) the amount of oil required to dissolve the ester since Katsuragi teaches that 0.01-10% bitterness relieving ester is needed to suppress the unpleasant mouthfeel of a botanical and the ester is dissolved in the oil prior to adding to the hard candy composition.

Regarding the ratio of bittering compound to bitterness relieving compound as recited in claims 8, 9, 35, 36, Katsuragi teaches a ratio of 1:0.1 to 1:1000 (Page 4, lines 43-47 and page 5, lines 9-13), which encompasses the ratio recited in claims 8, 9, 35 and 36.

Katsuragi does not explicitly teach the quantity of oil that is effective to suppress the unpleasant mouthfeel as recited in claims. However, to select any particular ratio of oil to botanical ratio such as 1.0/0.6 to 1/0.15 as recited in claims 8, 9, 35, 36 would have been obvious depending

- (1) the bitterness of the botanical included,
- (2) the amount of botanical included ,
- (3) the particular amount of ester required to suppress the unpleasant mouth feel of the botanical, and
- (4) the amount of oil required to dissolve the ester since Katsuragi teaches 1:0.1 to 1:1000 ratio of botanical (bittering compound) to ester (bitterness relieving agent) in the



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hard candy composition will be effective at suppressing the unpleasant mouth feel and the ester may be dissolved in oil prior to using.

(B) Claims 3 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsuragi in view of the combination of Sharma and Oravainen as applied to claims 1, 2, 4-9, 28, 29, 31-36 and 55 above, further in view of either Raymont (AU 9671904 A) or Emanuel-King (US 5248503).

Katsuragi teaches Ginkgo biloba added to lozenges/troches, but are silent in teaching a hard candy with Echinacea. Raymont and Emanuel King have been relied on as evidence of the conventionality of adding Echinacea to lozenges/troches/ breath dots etc. Raymont teaches the combination of active ingredients has a significant synergistic effect such that the therapeutic effect is greater than a merely additive effect. In particular, Raymont teaches that Echinacea provides immune system benefits (Page 2, lines 7-12, Page 3, lines 10-31, Page 5, line 22). Therefore, to include Echinacea would have been an obvious matter of choice, depending on the desired benefit of the botanical (e.g. improving the immune system). One would have been substituting one conventional botanical for another for the same purpose: providing a medical benefit in a hard candy form. One would have been further motivated include Echinacea to the troches or candy, to benefit from the synergistic effect of Ginkgo and Echinacea.

***Response to Arguments***

Applicant's arguments with respect to claims 1-9, 28-36 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's argument that Katsuragi does not teach the fat based bitterness relieving compound and that fats are only used as a carrier is not persuasive. Katsuragi teaches (1) "a bitterness-relieving agent which comprises an ester", which would not exclude components other than the ester (Page 3, line 3 and Claim 1), (2) the ester is formed by reacting mono or di-glycerides and a triglyceride contained therein (Page 3, lines 9-20) the compound is made from fatty acids esters with polycarboxylic acid which means that fatty acids have been esterified in the presence of carboxylic acid like citric acid. Fatty acids form ester bond with glycerol to form mono/di/tri-glycerides or fats. Thus the bitterness-reducing compound taught by Katsuragi is a fat based compound.

(3) the ester may be present with not more than 80% of other components (Page 3, lines 39-43),

(4) "it is also possible to dissolve the above-mentioned ester in an edible oil (triglyceride) before using" (Page 3, line 58 to Page 4, line 5), and

(5) the bitterness-relieving agent is 0.01-10% of a medical composition (Page 4, lines 43-47).

Thus, the term "bitterness-relieving agent" encompasses

(i) the ester compound containing fatty acids and triglycerides (not more than 80% triglycerides) after the reaction or

(ii) the ester dissolved in triglycerides.


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Chawla whose telephone number is (571) 272-8212. The examiner can normally be reached on 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jyoti Chawla  
Examiner  
Art Unit 1761

  
**KEITH HENDRICKS**  
**PRIMARY EXAMINER**